

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

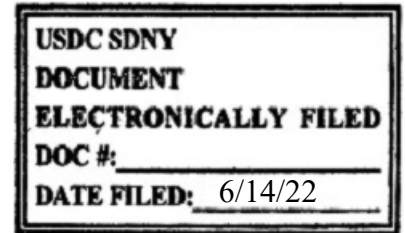
ECHO BAY PHARMACEUTICALS, LLC,

Plaintiff,

-against-

TORRENT PHARMA, INC.,

Defendant.



20-CV-6345 (BCM)

OPINION AND ORDER

In this diversity action between two pharmaceutical companies, plaintiff Echo Bay Pharmaceuticals, LLC (Echo Bay) alleges that defendant Torrent Pharma, Inc. (Torrent) breached both the express terms of the parties' Co-Development Settlement Agreement (CSA) and the covenant of good faith and fair dealing implied therein. Now before the Court is defendant's motion (Dkt. No. 94) to dismiss the Second Amended Complaint (SAC) (Dkt. No. 91) pursuant to Fed. R. Civ. P. 12(b)(6). For the reasons that follow: (i) the motion to dismiss will be granted; and (ii) Echo Bay will be given leave to replead, limited to its claim that Torrent breached the implied covenant by withdrawing its Abbreviated New Drug Application (ANDA) for a pharmaceutical product known as Fluocinonide without notice to Echo Bay.

I. BACKGROUND

A. Factual Allegations

On January 18, 2018, Echo Bay entered into the CSA with Torrent's predecessor, Bio-Farm Incorporated (BFI), for the purpose of developing and commercializing certain generic pharmaceutical products (the Products). SAC ¶¶ 20-21. Concurrently with the execution of the CSA, Torrent acquired BPI through a stock purchase agreement, obtained an assignment of BPI's rights and obligations under the CSA, and undertook to perform under the contract. *Id.* ¶¶ 26-28, 32. Torrent also became the owner of BPI's manufacturing facility in Levittown, Pennsylvania (the Levittown Facility), where the Products were to be developed. *Id.* ¶¶ 26, 32. Thereafter, BPI was

merged into Torrent and ceased to exist. *Id.* ¶ 29. Thus, "at all times from January 18, 2018 through the present, Torrent, as assignee of and/or successor in interest to BPI, was obligated to perform under the CSA." *Id.* ¶ 31. Echo Bay is a citizen of Illinois, while Torrent is a citizen of Delaware and New Jersey. SAC ¶¶ 2-4.

1. The CSA

Under the terms of the CSA, as amended on December 15, 2018 (SAC Exs. A, B), Echo Bay granted Torrent "the sole and exclusive worldwide rights" to "Commercialize each of the Products" specified in the contract, CSA § 2.2.¹ To that end, Torrent was "responsible to the Regulatory Authorities for carrying out Development activities," as well as "post-approval maintenance, prosecution, and fees." *Id.* § 3.3.² Echo Bay, for its part, was to "provide all reasonable assistance to [Torrent] regarding Development activities, including answering questions from the FDA [the U.S. Food and Drug Administration] or any other Regulatory Authority, regarding any Product." *Id.* § 3.4. It was also required to supply all necessary materials developed for product labels, packaging materials, and inserts. *Id.* § 4.2.

No generic drug can be sold to the public until the FDA approves the manufacturer's ANDA, which must show that the generic "has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved brand-name drug." *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142

¹ The CSA defines "Commercialization" as: "the commercial exploitation of any Product, directly or indirectly through Affiliates, including manufacturing, distribution, promotion, marketing, selling, or offering for sale, of any Product." CSA § 1.2.

² The CSA defines "Development" as: "all preclinical and clinic drug activities, including test method development and stability testing, toxicology, bioequivalency, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, and conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Regulatory Authority necessary for the manufacture, use, storage, import, export, transport, promotion, marketing and sale of any product." CSA § 1.5.

(2013) (quoting *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012)). "[T]his process is designed to speed the introduction of low-cost generic drugs to market." *Caraco*, 566 U.S. at 405.

The parties were to share equally the "Development Expenses" incurred by Torrent. CSA §§ 1.6, 3.1, 3.2. Echo Bay was required to pay its share on a quarterly basis upon receipt of an invoice from Torrent. *Id.* §§ 3.1, 3.2. In return, once a Product was Commercialized, Echo Bay would be entitled to 50% of the Net Revenue generated by that Product, less a Marketing Allocation. CSA §§ 1.7, 1.12, 2.4. However, "[n]othing contained in this Agreement is a warranty by the Company [Torrent] that any Commercialization in connection with this Agreement will achieve its aims or any other results." CSA § 2.5.

The CSA specifically gave "either Party" the right to "cease contributing Development expenses" with respect to a Product, at any time prior to the FDA's approval of the ANDA for that Product, "by notifying the other Party in writing[.]" CSA § 8.4(a). In addition, Torrent would be "deemed to have ceased Development of the Product," whether or not it provided "such written notice," if "no significant Development activities with regard to a Product have occurred over a given successive twelve (12) month period and such inactivity is not due to actions or omissions of a Third Party or events outside of the control of the Company." *Id.* In such an event, "the other Party . . . may choose to continue to develop [the Product] and initially incur one hundred percent (100%) of the remaining Development Expenses for such Product." *Id.*

2. The Active Products

The referenced Products are set out in Exhibit A of the CSA, and include the following Active Products:

- Fluocinolone (fluocinolone acetonide solution .01%);

- Fluocinonide (fluocinonide solution 5%);
- Pyridostigmine (pyridostigmine oral syrup); and
- Gabapentin (gabapentin solution).³

The FDA never approved an ANDA for any of the Active Products, SAC ¶¶ 56-76, 105, meaning that they could not be Commercialized. According to Echo Bay, this occurred because – despite its "reasonable expectation" that Torrent would "take prudent and necessary steps to develop such products in a timely manner so as to enjoy the revenue from the Commercialization of such products," *id.* ¶ 41 – Torrent failed adequately to "complete the remaining Development" of the Active Products. *Id.* ¶ 43. In particular, Echo Bay alleges that Torrent "botched" the development of the four Active Products, SAC ¶¶ 56-85, due largely to problems with its Levittown Facility, as follows:

Pyridostigmine. Torrent submitted an ANDA for Pyridostigmine on April 27, 2018. SAC ¶ 57. On February 20, 2019, the FDA determined that it could not "approve this ANDA in its present form" because of "major" deficiencies in "pharmaceutical quality, drug substance, drug product, and facilities inspection deficiencies." *Id.* ¶ 66 & Ex. G. The facilities inspection deficiencies stemmed from an FDA inspection of the Levittown Facility, "in which the FDA field investigator observed objectionable conditions that were conveyed to the facility representative." *Id.* Ex. G, ¶ 11. The FDA advised Torrent that "[s]atisfactory resolution of the observations is

³ Echo Bay lists a fifth Active Product, known as Felbamate (felbamate suspension). SAC ¶ 44. However, as Torrent points out, Felbamate was "assigned to Echo Bay in December 2018" when the parties amended their contract. Def. Mem. in Supp. of Mtn. to Dismiss SAC (Dkt. No. 95) at 3 n.2; Compl. Ex. B, ¶ 2.8. Two other Products originally listed in Exhibit A to the CSA (Mupirocin 2% nasal ointment and Eletriptan tablets) are not Active Products because the parties "mutually agreed to forgo Development and Commercialization" of those Products. SAC ¶ 44.

required before this ANDA may be approved," *id.*, but Torrent "failed to address" those conditions. *Id.* ¶ 67.

Later inspections in March and April 2019 turned up "numerous problems" at the Levittown Facility, which Torrent failed to rectify, ranging from inappropriately designed manufacturing equipment to deficient cleaning procedures. *Id.* ¶¶ 67-70. "In short," according to Echo Bay, "under Torrent's management and control the Levittown Facility was simply a mess," and "was not fit to produce any pharmaceuticals for any of Torrent's customers and partners, not just Echo Bay's Active Products." *Id.* ¶ 71. On October 28, 2019, the FDA issued a Warning Letter, SAC ¶ 72 & Ex. I, which among other things found that the facility was not adhering to "current good manufacturing practice" (CGMP), citing 21 C.F.R. parts 210-11, and therefore that Torrent's "drug products" manufactured in that facility were "adulterated" within the meaning of the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 351(a)(2)(B). SAC ¶ 72 & Ex. I, at 1.⁴

As a result of the "mounting issues" with the Levittown Facility, Torrent recognized "that it would not be able to produce pharmaceuticals there," SAC ¶ 86, and contacted "its other partners/customers" to inform them of the problems and "move [their] projects out of the facility to alternate manufacturing facilities." *Id.* ¶ 87. However, Torrent "did not extend the same courtesies to Echo Bay," *id.* ¶ 88, and instead "remained silent" and "tried to cover up and hide" the situation at the Levittown Facility by avoiding "Echo Bay's multiple inquiries and requests for status updates relating to the Active Products." *Id.* ¶ 89. Ultimately, Torrent ceased all Development and Commercialization efforts on the Active Products "in 2019," without telling

⁴ The FDA specifically referenced two drugs that Torrent had already introduced into interstate commerce, but that are not at issue in this action ("phenobarbital oral solution, USP" and hydrocortisone acetate suppositories, 25 mg."), and informed Torrent that selling those drugs violated 21 U.S.C. §§ 331(a) and (d). SAC Ex. I, at 2, 4-5.

Echo Bay that it was doing so, and "closed the Levittown Facility" to remodel and overhaul it – again, without telling Echo Bay that it was doing so. *Id.* ¶ 91. By closing the facility, Torrent "unilaterally made the decision to cease all further Development and Commercialization of the Active Products." *Id.* ¶ 93.⁵

Fluocinolone and Gabapentin. Torrent's predecessor submitted an ANDA for Fluocinolone on August 24, 2017. SAC ¶ 61. Torrent submitted an ANDA for Gabapentin on October 12, 2018. *Id.* ¶ 59. The parties expected FDA approval of these ANDAs on their "GDUFA goal date[s]" of June 23 and August 11, 2019, respectively, *id.* ¶¶ 60, 62, 65, but never received it.⁶

Fluocinonide. Torrent's predecessor submitted an ANDA for Fluocinonide on June 26, 2017. SAC ¶ 63. On July 26, 2020, it received "a Major Complete Response Letter from the FDA, noting continued issues with the Levittown Facility." *Id.* ¶ 74. On August 6, 2020, Torrent withdrew the Fluocinonide ANDA. *Id.* ¶¶ 75-76 & Ex. M. Even before that, according to Echo Bay, Torrent "had not performed any development activities for Fluocinonide for well over one

⁵ These allegations, as well as plaintiff's allegations (discussed below) that Torrent ceased its development efforts regarding Fluocinonide in 2019, SAC ¶¶ 74-79, are inconsistent with its more general allegation that "[a]t no time during the Term of the CSA" did Torrent "choose to cease contributing Development Expenses with any of the Products." *Id.* ¶ 47; *see also id.* ¶ 49 ("at no time during the Term of the CSA did there occur a period of time of twelve (12) or more successive months in which Torrent undertook no significant Development activities with respect to all of the Active Products"); *id.* ¶ 50 ("Torrent continued its Development work on the Active Products in 2019, and throughout the renovation of the Levittown Facility").

⁶ The SAC does not explain what a "GDUFA goal date" is. It appears, however, that when Torrent submitted the ANDAs at issue here, it sought priority review under the Generic Drug User Fee Amendments Act of 2017, Pub. L. 115-52 (August 18, 2017), 131 Stat 1005, "which expedites the timeline for drug approval decisions to get generics to the market more efficiently." *Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc.*, 2021 WL 3144897, at *6 (D.N.J. July 26, 2021). When priority review is granted, the FSA provides the applicant with a "goal date." *Id.*; *see also, e.g.*, SAC Ex. C (the "GDUFA II goal date" for "review" of the Pyridostigmine ANDA was February 26, 2019).

year." *Id.* ¶ 77.⁷ However, "Torrent never informed Echo Bay of Torrent's cessation of development of Fluocinonide, nor its withdrawal of the ANDA for Fluocinonide," *id.*, which Echo Bay first discovered, after this action was filed, through discovery. *Id.*

Echo Bay further alleges that Torrent failed to pay its share of Development Expenses for the Active Products "[o]n at least one occasion," SAC ¶ 95, involving Nines Consult Pharma LLC (Nines), which was engaged to perform services related to the development of Fluocinolone, Fluocinonide, and Gabapentin, at a cost of \$197,300. *Id.* ¶¶ 94-99 & Ex. L. Echo Bay paid for "all or some" of the \$197,300.00 Nines invoice, but Torrent refused to pay 50% of that cost. *See id.* ¶¶ 99-103. Echo Bay also complains that it dutifully paid Torrent more than \$1 million "for its share of Development Expenses" under § 3.1 of the CSA (including sums paid under a prior contract between Echo Bay and BPI), which was "squandered as a result of Torrent's abandonment of the Active Products and closing of the Levittown Facility." *Id.* ¶ 107.

B. Echo Bay's Claims

The Second Amended Complaint asserts a single cause of action, for breach of contract. SAC ¶¶ 116-28. Echo Bay alleges that Torrent breached numerous express provisions of the CSA: (i) §§ 7.1(c) and 9.5, which require the parties to comply with applicable laws and regulations; (ii) §§ 3.1 and 3.2, which govern the shared Development Expenses; (iii) the remainder of Article III (including §§ 3.3 and 3.4), concerning the parties' Development and Commercialization obligations; and (iv) § 8.4(a), which – as noted above – permits Torrent to "cease contributing Development Expenses" at any time before an ANDA has been approved for a Product and permits

⁷ Internal Torrent emails dating from February through April 2020 – filed under seal – show that in light of what the company assessed as a declining market for Fluocinonide, Torrent did not believe that it would be cost-effective to upgrade its facility to the extent necessary to manufacture that drug. SAC Ex. N (Dkt. No. 84-2). On April 10, 2020, a Torrent Vice President wrote, "I think we should withdraw the ANDA," and stated that he would "initiate that." *Id.* at ECF page 14.

Echo Bay, in those circumstances, to "choose to continue to develop" the product at its own expense. *See* SAC ¶ 118 (a)-(f).

Plaintiff further alleges that Torrent violated the covenant of good faith and fair dealing implied into all contracts by failing to "act reasonably, diligently and prudently in Development and Commercialization of the Active Products." SAC ¶ 121. Specifically, Echo Bay charges, Torrent violated the covenant (if not the express terms of the CSA) by, among other things, "failing to obtain ANDA approvals for the Active Products on or before their respective GDUFA dates"; failing to "promptly and properly remedy the defects" at the Levittown Facility; failing to keep Echo Bay apprised of its progress, the status of the Levittown Facility, and its "inability and/or refusal to Develop and Commercialize the Active Products"; and – more specifically – "failing to notify Echo Bay of its cessation of Development of Fluocinonide, and withdrawing the ANDA therefor without notifying or conferring with Echo Bay." *Id.* ¶ 122(a)-(i).

As a result of Torrent's breaches, Echo Bay alleges that it has suffered over \$15 million in damages, SAC ¶ 115, primarily because – in its view – had Torrent properly done its job, "Echo Bay's Pyridostigmine Product would have been the first on the market, would have enjoyed market exclusivity for at least 180 days,⁸ would have been the leading generic product of its kind, and would have been a significant commercial success generating millions of dollars of revenue for Echo Bay under the CSA." *Id.* ¶ 113.

⁸ Under the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iv), the first generic manufacturer to file an ANDA with respect to an eligible drug will, upon approval, "enjoy a period of 180 days of exclusivity (from the first commercial marketing of its drug)." *Actavis*, 570 U.S. at 143. "[T]his 180-day period of exclusivity can prove valuable." *Id.*

C. Procedural History

Echo Bay filed its initial Complaint on August 12, 2020, asserting three causes of action: breach of contract; breach of the implied duty of good faith and fair dealing under the CSA; and fraudulent concealment. (Dkt. No. 1.) Plaintiff filed its First Amended Complaint (FAC) (Dkt. No. 38) on October 2, 2020, consolidating its claims into a single cause of action alleging breach of both the express terms of the CSA (§§ 1.6, 3.1, 3.2, 7.1(c), 9.5, and Article III) and breach of the implied covenant. FAC ¶¶ 106-110. It did not, at that time, allege any breach of § 8.4(a), which it described as "inapplicable." *Id.* ¶ 51.

After the parties consented to jurisdiction by the assigned magistrate judge (Dkt. No. 39), Torrent filed a motion to dismiss the First Amended Complaint. (Dkt. No. 41.) Document discovery continued while that motion was briefed. (Dkt. No 45.) On July 20, 2021, Echo Bay moved for leave to further amend its pleading (Dkt. No. 81), and by order dated August 16, 2021 (8/16/21 Order) (Dkt. No. 90), the Court granted that motion, mooted Torrent's pending motion to dismiss. 8/16/21 Order, ¶¶ 1-3. Echo Bay filed its Second Amended Complaint on August 23, 2021, alleging for the first time that Torrent breached § 8.4(a) of the CSA by withdrawing the Fluocinonide ANDA and ceasing Development of that drug without telling Echo Bay that it had done so. The present motion followed, was fully briefed, and was argued on October 13, 2021. *See* Tr. of Oct. 13, 2021 Arg. (Tr.) (Dkt. No. 117) at 2-32.

II. ANALYSIS

A. Legal Standards

1. Motion to Dismiss

Fed. R. Civ. P. 8(a)(2) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." If a complaint fails to present "sufficient factual

matter, accepted as true, to state a claim to relief that is plausible on its face," the deficient claims must be dismissed pursuant to Fed. R. Civ. P. 12(b)(6). *Absolute Activist Value Master Fund Ltd. v. Ficeto*, 677 F.3d 60, 65 (2d Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. If the plaintiff has not "nudged [his] claims across the line from conceivable to plausible, [the] complaint must be dismissed." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

When considering a motion to dismiss made pursuant to Rule 12(b)(6), for failure to state a claim upon which relief can be granted, the trial court must "accept as true all factual statements alleged in the complaint and draw all reasonable inferences in favor of the non-moving party." *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007). However, those factual allegations "must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. Thus, "a pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (internal citations omitted) (quoting *Twombly*, 550 U.S. at 555, 557). The courts will not "unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Id.* at 678-79.

In addition to the facts alleged in the body of the complaint, the court may consider documents "attached to the complaint, incorporated by reference, or integral to the complaint," *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 106 (2d Cir. 2021), *cert. denied sub nom. U.S. ex rel. Foreman v. AECOM*, No. 21-1314, 2022 WL 1295727 (U.S. May 2, 2022). It may also consider matters of which judicial notice may be taken. *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 231 (2d Cir. 2016).

2. Breach of Contract

Under New York law, upon which both parties exclusively rely,⁹ a plaintiff asserting a claim for breach of contract claim must allege facts showing "(1) the existence of an agreement, (2) adequate performance of the contract by the plaintiff, (3) breach of contract by defendant, and (4) damages." *Boart Longyear Ltd. v. All. Indus., Inc.*, 869 F. Supp. 2d 407, 413 (S.D.N.Y. 2012) (quoting *Eternity Global Master Fund Ltd. v. Morgan Guar. Trust Co. of N.Y.*, 375 F.3d 168, 177 (2d Cir. 2004)). "Conclusory allegations" that a defendant breached the parties' contract are "insufficient to support a breach of contract claim." *Frontline Processing Corp. v. Merrick Bank Corp.*, 2014 WL 837050, at *2 (S.D.N.Y. Mar. 3, 2014) (citing *Berman v. Sugo LLC*, 580 F. Supp.

⁹ The CSA contains a New York jurisdiction and venue clause, CSA § 9.6, but no choice of law provision, and the parties nowhere explain why they both believe that New York law applies to a contract dispute between citizens of Illinois, Delaware, and New Jersey concerning generic drug development at a factory in Pennsylvania. Where the parties have consented to the law of the forum, however, the court may apply it. *See Prince of Peace Enterprises, Inc. v. Top Quality Food Mkt., LLC*, 760 F. Supp. 2d 384, 397 (S.D.N.Y. 2011), *adhered to on denial of reconsideration*, 2011 WL 650799 (S.D.N.Y. Mar. 14, 2011) ("[T]he parties have consented to application of New York law by briefing all issues under the law of New York."); *O'Grady v. BlueCrest Cap. Mgmt. LLP*, 111 F. Supp. 3d 494, 500 fn.2 (S.D.N.Y. 2015), *aff'd*, 646 F. App'x 2 (2d Cir. 2016) (applying New York law even though the agreement at issue stated that it was governed by Delaware law, because "the parties cite to New York law in their memoranda of law and the Court accepts that as the relevant law"). Moreover, in the absence of any "actual conflict of laws" between the potentially relevant jurisdictions, "a choice-of-law analysis is unnecessary and New York law will apply." *Harley v. Mins. Techs. Inc.*, 2014 WL 5017830, at *3 (S.D.N.Y. Sept. 26, 2014) (internal quotation marks and citations omitted). No such "actual conflict" exists here. *See VistaJet Ltd. v. Paragon Jets LLC*, 2022 WL 431431, at *5 (E.D.N.Y. Jan. 10, 2022) (finding "no conflict between New York and New Jersey contract law"), *report and recommendation adopted*, 2022 WL 426183 (E.D.N.Y. Feb. 11, 2022); *In re Unisys Sav. Plan Litig.*, 2001 WL 910945, at *3 fn.8 (E.D. Pa. Aug. 9, 2001) ("it appears neither New York nor Pennsylvania law conflicts with general contract interpretation principles"), *aff'd sub nom. Zylla v. Unisys Corp.*, 57 F. App'x 79 (3d Cir. 2003); *Andrichyn v. TD Bank, N.A.*, 93 F. Supp. 3d 375, 386 (E.D. Pa. 2015) ("Both Pennsylvania and New York recognize that every contract imposes upon each party a duty of good faith and fair dealing in its performance and its enforcement.") (internal quotation marks and citations omitted); *UBS AG v. Cournot Fin. Prod., LLC*, 2010 WL 3001884, at *1-2 (S.D.N.Y. July 26, 2010) (applying both New York and Delaware law in dismissing claims for breach of contract and breach of the implied covenant of good faith and fair dealing).

2d 191, 202 (S.D.N.Y. 2008)). The complaint must specify which provisions of the contract were allegedly breached, and the conduct that constituted that breach. *Glob. Media Corp. v. Gateway Distributors, Ltd.*, 2007 WL 2589535, at *3 (S.D.N.Y. Aug. 28, 2007).

3. Breach of the Covenant of Good Faith and Fair Dealing

In New York (as in other jurisdictions), all contracts include an implied covenant of good faith and fair dealing, *see Van Valkenburgh, Nooger & Neville, Inc. v. Hayden Pub. Co.*, 30 N.Y.2d 34, 45, 330 N.Y.S.2d 329 (1972), which is breached "when a party to a contract acts in a manner that, although not expressly forbidden by any contractual provision, would deprive the other party of the right to receive the benefits under their agreement." *Prakhin v. Fulton Towers Realty Corp.*, 122 A.D.3d 601, 602, 996 N.Y.S.2d 85, 88 (2d Dep't 2014); *see also Leberman v. John Blair & Co.*, 880 F.2d 1555, 1560 (2d Cir. 1989) ("The covenant of good faith and fair dealing precludes each party from engaging in conduct that will deprive the other party of the benefits of their agreement.") (internal citations and quotation marks omitted). However, the implied covenant "cannot be used to add wholly new terms to the contract," *Wagner v. JP Morgan Chase Bank*, 2011 WL 856262, at *5 (S.D.N.Y. Mar. 9, 2011) (Sullivan, J.) (quoting *Macfarlane & Assocs., Inc. v. Noxell Corp.*, 1994 WL 369324, at *3 (S.D.N.Y. July 13, 1994)), and "will not impose an obligation that would be inconsistent with the terms of the contract." *Iskalo Elec. Tower LLC v. Stantec Consulting Servs., Inc.*, 174 A.D.3d 1420, 1423, 107 N.Y.S.3d 202, 206 (4th Dep't 2019) (internal citations and quotation marks omitted); *see also Trireme Energy Holdings, Inc. v. Innogy Renewables US LLC*, 2021 WL 3668092, at *5 (S.D.N.Y. Aug. 17, 2021) ("a court may not imply a covenant inconsistent with terms expressly set forth in an agreement").

B. Plaintiff Cannot State a Claim for Breach of Any Express Term of the CSA

1. Sections 7.1(c) and 9.5

Sections 7.1 and 9.5 generally prohibit the parties to the CSA from violating the law. In § 7.1(c), Torrent and Echo Bay represent and warrant that "[t]he execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable laws or regulations of any governmental instrumentality or any contractual obligation of such Party, and (ii) do not conflict with, or constitute a default or require any consent under, any contractual obligation of such Party." Section 9.5 requires both parties to "comply with all Federal, State and local laws, rules and regulations applicable to its obligations under this Agreement including, without limitation, any anti-bribery, anti-corruption and anti-kickback laws, rules and regulations."

Echo Bay contends that Torrent breached one or both of these provisions by incurring "multiple regulatory failures noted by the FDA." SAC ¶ 118(a). Section 7.1(c), which is a standard clause in many commercial contracts, is designed to ensure that the contract itself, including the parties' contracted-for performance, does not violate public policy. *See Pittsburg SNF LLC v. Pharmerica E., Inc.*, 2011 WL 13136001, at *2 & n.2 (E.D. Tex. Sept. 7, 2011), *report and recommendation adopted*, 2011 WL 13141646 (E.D. Tex. Sept. 29, 2011).¹⁰ It does not contain or

¹⁰ In *Pittsburg SNF*, the question was whether certain self-dealing Pharmacy Service Agreements (PSAs) between a group of nursing homes and an affiliated institutional pharmacy, which created a "binding drug referral system" that guaranteed above-market profits for the pharmacy at the expense of the nursing homes and their residents, violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and other laws. 2011 WL 13136001, at *2. The plaintiff (which had purchased the nursing homes from the prior owners) sued the pharmacy for, *inter alia*, breach of various provisions of the PSAs, including § 8(e), which stated that "the performance of . . . [each] . . . party's obligations hereunder do not . . . conflict with or violate any requirement of applicable laws or regulations[.]" *Id.* at *2 & n.2. Without resolving the ultimate question, the court denied the pharmacy's motion to dismiss the breach of contract claim, thus permitting the nursing homes to proceed on the theory that the PSAs themselves violated the law. *Id.* at *3-4.

imply a promise that Torrent will never incur a regulatory infraction during its future performance under that contract.

Section 9.5 is forward-looking, but according to Torrent its language – specifically listing the "anti-bribery, anti-corruption and anti-kickback laws" – makes it clear that it is aimed at major misconduct, not regulatory shortfalls that cause delays in ANDA approval. *See* Def. Mem. in Supp. of Mtn. to Dismiss FAC (Dkt. No. 42) at 11 ("Put simply, this provision does not require the parties to always pass FDA inspections, it requires them not to bribe the inspector.").¹¹ Echo Bay, in response, points out that in its Warning Letter (SAC Ex. I), the FDA "specifically notified Torrent that its performance violated FDA regulations, including a citation to the specific regulations in question." Pl. Mem. in Opp. to Mtn. to Dismiss FAC (Dkt. No. 44) at 7.

The Court notes, however, that the violative conduct described in the Warning Letter was the sale of phenobarbital oral solution and hydrocortisone acetate suppositories, which according to the FDA violated 21 U.S.C. §§ 331(a) and (d) due to the CGMP deficiencies noted at the Levittown Facility, where they were manufactured. SAC Ex. I. These drugs were not produced for or in partnership with Echo Bay, and are not subject to the CSA. Conversely, there is no mention in the Warning Letter of any of the Active Products (presumably because none of them had yet been introduced in interstate commerce), and no claim by the FDA that Torrent's *development* activities with respect to the Active Products violated the FDCA or any other statute or regulation.¹² Consequently, even assuming, *arguendo*, that FDCA violations (like violations of the

¹¹ With respect to the "unamended portion of the SAC," the parties were permitted to rely on their previously-submitted briefs in support of and in opposition to the motion to dismiss the FAC. *See* 8/16/21 Order ¶ 4.

¹² Similarly, in its earlier letter declining to approve the Pyridostigmine ANDA, the FDA stated that the Levittown Facility was "inadequate" in various ways, SAC Ex. G, at 1, but did not conclude that Torrent had committed any statutory or regulatory violation with respect to Pyridostigmine.

anti-bribery, anti-corruption, and anti-kickback laws) could constitute a breach of CSA § 9.5, Echo Bay has not pled such a breach here.

2. Sections 3.1 and 3.2

Sections 3.1 and 3.2 of the CSA govern the payment of Development Expenses. Importantly, § 1.6 defines Development Expenses solely as *Torrent's* expenses.¹³ Section 3.1 states that the parties are to each pay half of those Development Expenses ("whether resulting from an invoice from a third party or an internal expense of the Company") and that Torrent is to invoice Echo Bay for its share on a quarterly basis. Section 3.2 governs how Echo Bay is to pay its share (including, after a Product has been Commercialized, by deducting the Development Expenses it owes from the Net Revenue Share due to it under § 2.4).¹⁴ There is no provision in the CSA that requires *Torrent* to pay or reimburse *Echo Bay* for expenses incurred by the latter in connection with the Products. Consequently, Echo Bay's allegation that Torrent failed to pay its share of the

Rather, as the FDA explained, Torrent had not yet demonstrated that the Pyridostigmine ANDA should be approved. *See id.* ("we cannot approve this ANDA in the present form"); *id.* ¶ 11 ("[s]atisfactory resolution" of the "objectionable conditions" at the facility was "required before the ANDA may be approved.").

¹³ Section 1.6 reads, in full: "'Development Expenses' means all costs *incurred by Company* that are related to the Development of any Product, including any changes to a Product necessary to maintain or update the related ANDA and also, including all such costs incurred with regard to any Product that is eventually not Commercialized or not submitted to any Regulatory Authority for approval or clearance; provided, however, that (a) with respect to costs related to the Development of the Products that were incurred by Company prior to the Effective Date, the Development Expenses shall be limited to the amount set forth in the 'Spend till Date' column in the table on Schedule 1.6 (the 'Pre-Effective Date Development Expenses') and (b) with respect to costs related to the Development of the Products to be incurred by Company after the Effective Date, Company will not incur any costs that exceed the amounts set forth in the 'Future Estimate' column in the table on Schedule 1.6 without the Company's prior, written approval, such approval not to be unreasonably withheld." CSA § 1.6 (emphasis added.)

¹⁴ If Echo Pay fails to pay its share of the Development Expenses, Torrent's "sole remedy" is "to terminate this Agreement[.]" CSA § 3.2. In other words, the parties agreed that there would be no damages remedy for a breach of §§ 3.1 or 3.2.

Nines invoice, SAC ¶¶ 95-104, 111, 118(b), fails to state a claim for breach of contract. Similarly, its claim that Torrent "squandered" Development Expenses previously invoiced and paid, *id.* ¶¶ 107-09, 118(c), fails to state a claim, because the CSA nowhere guarantees that Torrent's Development efforts would be successful, much less that they would result in profits.

3. Article III

Echo Bay alleges broadly that Torrent violated the CSA by "failing to perform its Development and Commercialization obligations under Article III of the CSA." SAC ¶ 118(d). Article III contains four provisions. Sections 3.1 and 3.2 are addressed above; no breach of those sections has been pleaded. Section 3.4 requires Echo Bay to cooperate with Torrent by providing "reasonable assistance." Plaintiff's Article III claim therefore turns on § 3.3, which makes Torrent "responsible to Regulatory Authorities for carrying out Development activities and post-approval maintenance, prosecution and fees." CSA § 3.3.

In its brief, Echo Bay explains that, in its view, Torrent violated § 3.3 because it "was under an obligation to perform Development activities with respect to the Active Products, which it failed to do." Pl. Mem. in Opp. to Mtn. to Dismiss FAC, at 10; *see also id.* at 11 (Torrent violated § 3.3 because it "failed to develop the Active Products in question"). To the extent the claim is that Torrent never undertook *any* Development Activities with respect to the Active Products, however, the factual allegations set forth in the SAC quite clearly contradict it. *See, e.g.*, SAC ¶ 46 ("Torrent commenced, continued and undertook Development efforts of the Active Products at its newly acquired Levittown Facility"); *id.* ¶ 50 ("Albeit unsuccessfully, Torrent continued its Development work on the Active Products in 2019[.]"); *id.* ¶¶ 57, 59, 61, 63 (Torrent or its predecessor submitted ANDAs for each of the Active Products); *see also* Pl. Mem. in Opp. to Mtn. to Dismiss FAC, at

12 (conceding that the SAC "clearly show[s] Torrent undertaking the development of the products").

Since Echo Bay does not and cannot allege that Torrent failed outright to "perform Development activities" with respect to the Active Products, its claim with respect to § 3.3 must be that Torrent had an obligation perform those activities *successfully* (or at least diligently), which – in plaintiff's view – it failed to do in various ways, including by failing to promptly address the conditions at the Levittown Facility and by withdrawing the Fluocinonide ANDA and "ceasing" development activities as to that Product. However, the contract does not, on its face, require either success or any particular level of effort, *see* CSA §§ 2.5, 3.3, and it is a fundamental tenant of contract law that the courts may not "through their interpretation of a contract, add or excise terms or distort the meaning of any particular words or phrases, thereby creating a new contract under the guise of interpreting the parties' own agreements." *Nomura Home Equity Loan, Inc., Series 2006-FM2, by HSBC Bank USA, Nat'l Ass'n v. Nomura Credit & Cap., Inc.*, 30 N.Y.3d 572, 581, 69 N.Y.S.3d 520, 525 (N.Y. 2017).

In this case, moreover, Echo Bay and Torrent were sophisticated parties who understood the ANDA process, and whose economic interests were well aligned as a result of their anticipated 50-50 revenue split. Had Echo Bay nonetheless bargained for milestones tied to GDUFA goal dates, or a "best efforts" clause, the parties "certainly could have included such language in the contract[]." *MBIA Ins. Corp. v. Countrywide Home Loans, Inc.*, 105 A.D.3d 412, 413, 963 N.Y.S.2d 21, 23 (1st Dep't 2013). "It is not the place of the Court to imply such a provision after the fact when sophisticated, counseled businesspeople did not explicitly include it." *Wagner*, 2011 WL 856262, at *5.

Not only did the parties fail to include the necessary language in § 3.3; they expressly agreed, in § 8.4, that Torrent could "choose to cease contributing Development Expenses," that is, it could choose to stop work on a Product before any ANDA was approved – which is exactly what it is alleged to have done. To interpret § 3.3 as Echo Bay now proposes would read § 8.4 out of the CSA entirely, which this Court cannot do. *See Nomura Home Equity Loan*, 30 N.Y.3d at 581, 69 N.Y.S.2d at 524 ("[A] contract must be construed in a manner which gives effect to each and every part, so as not to render any provision 'meaningless or without force or effect.'") (quoting *Ronnen v. Ajax Elec. Motor Corp.*, 88 N.Y.2d 582, 589, 648 N.Y.S.2d 422, 424 (1996)). Consequently, the SAC fails to plead a violation of CSA § 3.3.

4. Section 8.4(a)

Finally, Echo Bay alleges that Torrent violated an express provision of the CSA by "failing to assign the items required under Section 8.4(a)(ii) to Echo Bay," SAC ¶ 118(e), including all intellectual property" and all "regulatory filings and approvals" for Fluocinonide. *Id.* ¶ 83. Echo Bay did not "waive" this claim by failing to include it in the FAC.¹⁵ However, subsection (ii)

¹⁵ Citing *Rosenshein v. Kleban*, 918 F. Supp. 98, 104 (S.D.N.Y. 1996), Torrent argues that plaintiff "should not be permitted to now proceed on its § 8.4 theory, which it previously waived for strategic reasons, after pursuing this litigation for the past year under entirely different and inconsistent theories and allegations." Def. Mem. in Supp. of Mtn. to Dismiss SAC, at 7. In *Rosenshein*, however, the court held that plaintiffs were "judicially estopped" from asserting certain claims after failing to disclose those claims in an earlier bankruptcy proceeding, thereby inducing the bankruptcy court to approve a plan of reorganization on false pretenses. *Id.* at 104-05. Judicial estoppel is an equitable doctrine that "functions generally to bar litigants from taking inconsistent positions in successive suits." *Clark v. All Acquisition, LLC*, 886 F.3d 261, 265 (2d Cir. 2018). It applies where: (1) "the party against whom the estoppel is asserted took an inconsistent position in a prior proceeding," and (2) "that position was adopted by the first tribunal in some manner, such as by rendering a favorable judgment." *Id.* at 266 (internal quotation marks and citations omitted); accord *Bates v. Long Island R. Co.*, 997 F.2d 1028, 1038 (2d Cir. 1993). Here, although Echo Bay's theories of liability have evolved somewhat over two amendments, no court "adopted" its prior allegations as the basis for a judgment or other favorable ruling. Judicial estoppel therefore has no application here.

comes into play only after Torrent has "ceased Development of [a] Product" *and* Echo Bay has "cho[sen] to continue to develop" the Product "and initially incur 100% (100%) of the remaining Development Expense for such Product." CSA § 8.4(a). Although Echo Bay alleges vaguely that had it taken over the Development of Fluocinonide – at some point before Torrent withdrew the ANDA – it would have enjoyed "revenues associated with Commercialization of the product," SAC ¶ 84, it does not allege that it ever "cho[se] to continue to develop" Fluocinonide, much less that it was ever willing to pay for 100% of the remaining development costs.¹⁶ Consequently, once again, plaintiff has failed to plead a violation of any express term of the CSA.

C. Plaintiff May Be Able to State a Claim for Breach of the Implied Covenant

Turning from the express terms of the CSA to the covenant of good faith and fair dealing, Echo Bay argues that this Court should imply into the CSA *either* a duty to perform its Development activities in a "a reasonable and prudent manner," Pl. Mem. in Opp. to Mtn. to Dismiss SAC (Dkt. No. 100) at 4, which would prohibit it from ceasing Development "at any time for any reason," *id.* at 6, *or* – in the alternative – a duty "to inform Echo Bay" if and when it stopped Development of a Product, so that Echo Bay could exercise its rights under § 8.4(a). *Id.* at 4.

1. Implied Obligation to Use Reasonable Efforts

The first prong of plaintiff's argument fails because, as noted above, the duty that Echo Bay seeks to imply into the CSA is not merely absent from the face of the contract, *see Wagner*, 2011 WL 856262, at *5 ("[A]n implied covenant of good faith cannot be used to add wholly new terms

¹⁶ At oral argument, Echo Bay's counsel conceded that plaintiff never asked for its § 8.4(a)(ii) rights as to Fluocinonide, explaining that "[p]harmaceuticals are time-sensitive products in an evolving market" and therefore that "the value of the drug, of learning about it in the last few months, with the ANDA being withdrawn, is not what the value of the drug would have been to us had we been told at the time that Torrent . . . decided that it was not going to proceed with this drug." Tr. at 18:18-24, 20:25-21:7.

to the contract.”); *Don King Prods. Inc. v. Douglas*, 742 F. Supp. 741, 767 (S.D.N.Y.1990) (“The implied covenant does not . . . operate to create new contractual rights.”); it is “inconsistent with terms expressly set forth in [the] agreement,” *Trireme Energy Holdings*, 2021 WL 3668092, at *9, including the *express* right, granted to Torrent in § 8.4(a), to “choose to cease contributing Development Expenses,” either by notifying the other party in writing or simply by engaging in no significant Development activities for 12 months. *See also Times Mirror Mags., Inc. v. Field & Stream Licenses Co.*, 294 F.3d 383, 394 (2d Cir. 2002) (“no obligation can be implied that would be inconsistent with other terms of the contractual relationship”) (quoting *Dalton v. Educ. Testing Serv.*, 87 N.Y.2d 384, 389, 639 N.Y.S.2d 977, 980 (1995)).

Echo Bay's characterization of the CSA as conferring an “exclusive license” on Torrent, *see* Pl. Mem. in Opp. to Mtn. to Dismiss FAC at 16-18, does not require a different result. Pointing to § 2.2 of the CSA (in which Echo Bay “grants to Company, and Company accepts, the sole and exclusive worldwide rights to Commercialize each of the Products”), Echo Bay relies on a line of New York cases holding “that a contract to pay royalties contains an implied covenant to use reasonable efforts to market the product – where the only compensation called for by an exclusive license contract was payment of royalties.” *New Paradigm Software Corp. v. New Era of Networks, Inc.*, 2002 WL 31749396, at *11 (S.D.N.Y. Dec. 9, 2002) (collecting cases). The theory behind these cases is that “it would be unfair to place the productiveness of the licensed property solely within the control of the licensee, thereby putting the licensor at his mercy, without imposing an obligation to exploit upon the licensee. In effect the court is merely enforcing an obligation which the parties overlooked expressing in their contract or which they considered unnecessary to be expressed.” *Id.* (quoting *Vacuum Concrete Corp. v. American Mach. & Foundry Co.*, 321 F. Supp. 771, 772-73 (S.D.N.Y. 1971)).

Here, however, Echo Bay was not wholly at the mercy of Torrent, because if Torrent chose not to "exploit" the grant (and if Echo Bay knew about that choice), Echo Bay could revoke its grant and secure for itself not only "the right to complete the Development" but also "the right to Commercialize" the Product. CSA ¶ 8.4(a)(ii). *See* Def. Reply Mem. in Supp. of Mtn. to Dismiss SAC (Dkt. No. 103) at 1 (under the CSA, "a party that is unhappy with the pace of development may choose pursuant to Section 8.4 to take over development for itself"). Moreover, the parties did not "overlook" the term that Echo Bay would have the Court supply. *Vacuum Concrete Corp.*, 321 F. Supp. at 773. To the contrary: they expressly gave Torrent the right to "cease" its Development Activities, balanced by Echo Bay's right to Develop and Commercialize the Product itself, for its sole benefit (after repaying, out of Net Revenues, the Development Expenses that Torrent previously contributed). CSA ¶ 8.4(a)(ii). Echo Bay does not cite, and the Court has not located, any authority for the proposition that exclusive license agreements are exempt from the well-settled rule that the implied covenant "will never impose an obligation which would be inconsistent with the other terms of the contractual relationship." *Metro. Life Ins. Co. v. RJR Nabisco, Inc.*, 716 F. Supp. 1504, 1517 (S.D.N.Y. 1989) (internal quotation marks and citations omitted).

2. Implied Notice Obligation

Plaintiff is on stronger ground when it argues that Torrent had an implied obligation to communicate its decision to withdraw the Fluocinonide ANDA so that Echo Bay could effectively exercise its right to Develop and Commercialize that Product itself. The implied covenant is breached "when a party to a contract acts in a manner that, although not expressly forbidden by any contractual provision, would deprive the other party of the right to receive the benefits under their agreement." *Prakhin*, 122 A.D.3d at 602, 996 N.Y.S.2d at 88; *see also Leberman*, 880 F.2d

at 1560 ("The covenant of good faith and fair dealing precludes each party from engaging in conduct that will deprive the other party of the benefits of their agreement.") (internal citations and quotation marks omitted); *Metro. Life Ins. Co.*, 716 F. Supp. at 1517 (where one party has, without "technically" breaching the express terms of the contract, "effectively deprived the other [party] of those express, explicitly bargained-for benefits," the court "will read an implied covenant of good faith and fair dealing into a contract to ensure that neither party deprives the other of 'the fruits of the agreement.'") (quoting *Greenwich Vill. Assocs. v. Salle*, 110 A.D.2d 111, 115, 493 N.Y.S.2d 461, 464 (1st Dep't 1985)).

Under New York law, "[t]he implied covenant of good faith and fair dealing may give rise to a notice requirement," *42-50 21st St. Realty LLC v. First Cent. Sav. Bank*, 2022 WL 1004187, at *3 (E.D.N.Y. Apr. 4, 2022), where necessary to protect the other party's "express, explicitly bargained-for benefits." *Metro. Life Ins. Co.*, 716 F. Supp. at 1517. *See, e.g., Sterling Nat'l Bank v. Goldberg*, 277 A.D.2d 45, 47, 715 N.Y.S.2d 409, 411 (1st Dep't 2000) (summary judgment should have been denied where "issues of fact exist as to whether Sterling breached the implied covenant of good faith and fair dealing when it precipitously cut off the debtors' line of credit without notice"); *Components Direct, Inc. v. Eur. Am. Bank & Trust Co.*, 175 A.D.2d 227, 229-30, 572 N.Y.S.2d 359, 361 (2d Dep't 1991) (although defendant EAB "had an absolute right to terminate credit under the loan agreement," the "obligation of good faith would require a period of notice to allow the corporate plaintiff a reasonable opportunity to seek alternate credit"); *Wells v. Alexandre*, 130 N.Y. 642, 645, 29 N.E. 142, 143 (1891) (inferring "a covenant to give such notice" because "any other construction would make the contract unreasonable, and place one of the parties entirely at the mercy of the other"). Here, Echo Bay has the "express, explicitly bargained-for" right to take over the Development and Commercialization of the Products covered by the CSA within

90 days "of either written notice that [Torrent] chooses not to contribute additional Development Expenses with regard to such Product or the date that [Torrent] is deemed to have ceased Development of the Product." CSA § 8.4(a)(ii). If Echo Bay elects to do so, it is entitled to the benefit of Torrent's Development activities to date, including "all regulatory filings and approvals" related to the Product. *Id.*¹⁷ In the case of Fluocinonide, however, Echo Bay alleges that Torrent secretly withdrew the ANDA on August 6, 2020, SAC ¶¶ 75, 80, but concealed that fact until after this action was filed the following year. *Id.* ¶ 81 ("it is only through documents received in discovery in this case that Echo Bay first learned of Torrent's . . . withdrawal of the ANDA"). Assuming the truth of these allegations, as required for purposes of the instant motion, Torrent not only prevented Echo Bay from timely exercising its rights under § 8.4(a) (so as to take advantage of favorable but fleeting market conditions); it also deprived Echo Bay of one of the specifically-enumerated "fruits of the agreement," namely, an assignment of Torrent's "regulatory filings." Thus, although Torrent is correct that § 8.4(a) ordinarily permits it to "cease development with or without communicating to Echo Bay," Def. Reply Mem. in Supp. of Mtn. to Dismiss SAC at 2, Echo Bay has plausibly alleged that in the specific circumstances presented here, Torrent engaged in conduct that "deprive[d] the other party of the benefits of their agreement," *Leberman*, 880 F.2d at 1560, thereby violating the covenant of good faith and fair dealing.

However, Echo Bay has failed, thus far, to plausibly allege that it suffered any damages caused by that violation. *See LNC Invs., Inc. v. First Fid. Bank, N.A. New Jersey*, 173 F.3d 454, 464 (2d Cir. 1999) ("[C]ausation is required to recover damages for breach of contract."); *Point Prods. A.G. v. Sony Music Ent., Inc.*, 215 F. Supp. 2d 336, 341 (S.D.N.Y. 2002) ("In a breach of

¹⁷ On December 5, 2018, Echo Bay exercised that right with respect to Felbamate, which it was able to do because Torrent's predecessor stipulated, in writing, that it "cho[se] to cease contributing development expenses with regard to" that Product. SAC Ex. B, § 2.8.

contract action, the plaintiff must demonstrate more than simply that defendant breached its contract and that the plaintiff suffered damage. Plaintiff cannot recover if it would have suffered the harm regardless of defendant's actions."), *opinion amended on reconsideration*, 2002 WL 31856951 (S.D.N.Y. Dec. 19, 2002). While plaintiff does assert in conclusory terms that Torrent "caused significant damages to Echo Bay by depriving it of its ability to continue development of Fluocinonide and the revenues associated with Commercialization of the Product," SAC ¶ 84, it fails to allege the necessary *factual* predicates for such a claim, including facts demonstrating that *if* given notice before Torrent withdrew the ANDA on August 6, 2019, it *would have* exercised its rights under § 8.4(a), *would have* brought Fluocinonide to market, and *would have* earned a profit on the drug.

III. CONCLUSION

For the reasons set forth above, Torrent's motion to dismiss the Second Amended Complaint (Dkt. No. 91) is GRANTED.

Although Echo Bay has already amended its pleading twice, it has "not yet had an opportunity to do so in response to an opinion of the Court." *Reiner v. Teladoc Health, Inc.*, 2020 WL 7028638, at *6 (S.D.N.Y. Nov. 30, 2020) (granting motion to dismiss with leave to replead). In such circumstances, leave to further amend must be considered, and is appropriately allowed unless the Court concludes that amendment would be futile. *Id.* Here, Echo Bay has adequately alleged a breach of the covenant of good faith and fair dealing in connection with Torrent's withdrawal of the Fluocinonide ANDA, and may be able, on repleading, to allege a cognizable damages theory as well. However, there are no other or different facts that it could allege to salvage the remainder of its case. Leave to amend is therefore GRANTED for the limited purpose of

repleading its breach-of-covenant claim arising out of the withdrawal of the Fluocinonide ANDA.

The Third Amended Complaint must be filed within 30 days.

Dated: New York, New York
June 14, 2022

SO ORDERED.

A handwritten signature in blue ink, appearing to read "Barbara Moses", is written over a horizontal line.

BARBARA MOSES
United States Magistrate Judge